

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Article 36 and Rule 70)

REC'D 23 MAR 2005



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| Applicant's or agent's file reference BCS 02-4009 | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416) | |
| International application No. PCT/EP 03/15007 | International filing date (day/month/year) 08.12.2003 | Priority date (day/month/year) 06.12.2002 |
| International Patent Classification (IPC) or both national classification and IPC C12N15/82 | | |
| Applicant BAYER CROPSCIENCE S.A. et al. | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:
- I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

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| Date of submission of the demand 22.06.2004 | Date of completion of this report 24.03.2005 |
| Name and mailing address of the International preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016 | Authorized Officer Blanco Urgoiti, B Telephone No. +31 70 340-4148  |

3. INVENTIVE STEP

- 3.1 The present application meets the criteria of Article 33(1) PCT, because the subject-matter of claims 1-16 involves an inventive step in the sense of Article 33(3) PCT.
- 3.2 The document D1 is regarded as being the closest prior art for the subject-matter of claim 1.
- 3.3 In the light of D1, the problem to be solved is the provision of a fertile transplastomic leguminous plant. The solution provided is a fertile transplastomic soybean.
- 3.4 This solution is regarded as involving an inventive step. The prior art (as for example D1 or D3) shows that a solution to the problem to which the present invention relates was continually being sought, and this long felt want is satisfied by the invention. The same holds for related claims 2-16.

4. INDUSTRIAL APPLICABILITY

- 4.1 The subject-matter of claims 1-16 seems to be susceptible of industrial applicability as defined in Article 33(4) PCT.

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|------|
| Novelty (N) | Yes: Claims | 1-16 |
| | No: Claims | |
| Inventive step (IS) | Yes: Claims | 1-16 |
| | No: Claims | |
| Industrial applicability (IA) | Yes: Claims | 1-16 |
| | No: Claims | |

2. Citations and explanations

see separate sheet

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Reference is made to the following documents, D2 has been introduced by the applicant:

- D1: WO 99/10513 A (DANIELL HENRY ;UNIV AUBURN (US)) 4 March 1999 (1999-03-04)
- D2: DANIELL H. ET AL. (2004); "Chloroplast genetic engineering" in "Molecular Biology and Biotechnology of Plant Organelles", pages 443-490. Eds: Daniell H. and Chase Ch.; Kluwer Academic Publishers, The Netherlands.
- D3: ZHANG, X.-H. ET AL.: "Plastid transformation of soybean suspension cultures" JOURNAL OF PLANT BIOTECHNOLOGY, vol. 3, no. 1, January 2001, pages 39-44

2. NOVELTY

- 2.1 The document D1 discloses transplastomic soybeans (see example 6, page 49), bearing the marker gene *Aad* under the *prn* promoter (see fig. 7A), introduced in the plastid genome by particle bombardment of leave explants. Shoots are shown in Figure 15, but nothing is mentioned about the fertility of the transplastomic soybeans obtained. Transplastomic tobaccos bearing two genes are also disclosed.
- 2.2 Document D2 relates to a review by the inventor of D1, and published after the filing date of the present application, acknowledging in an implicit way that the soybeans obtained in D1 were not fertile (see pages 453-454 under point 5.5). It can be concluded that D1 is not an enabling disclosure of a fertile transplastomic soybean.
- 2.3 In view of D1 the present application meets the criteria of Article 33(1) PCT, because the subject-matter of claims 1 to 16 is new in the sense of Article 33(2) PCT.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/15007

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-23 as originally filed

Sequence listings part of the description, Pages

1-22 as originally filed

Claims, Numbers

1-16 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets: